SEP 2 0 2001

K002241

Date of Summary: July 20, 2000

ADMINISTRATIVE INFORMATION

Manufacturer Name: Quantum BioEngineering, Ltd.
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Plantation, FL 33324

Official Contact: Raul R. Mena, DMD
Telephone (954) 474-4707
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Representative/Consultant: Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, CA 92130
Telephone (858) 792-1235
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DEVICE NAME

Classification Name: Endosseous dental implant

Trade/Proprietary Name: Quantum™ Versatility™ (QVS™) Dental Implant System

Common Name: Dental Implant

ESTABLISHMENT REGISTRATION NUMBER

Quantum BioEngineering, Ltd. is not yet registered with FDA.

DEVICE CLASSIFICATION

Endosseous dental implants have been classified by FDA as Class III devices under a final order published in the Federal Register of August 12, 1987, as shown in 21 CFR 872.3640. Abutments to such implants are considered by FDA to be Class III devices inasmuch as they are used as accessories to or are used with endosseous dental implants. The device is reviewed by the Dental Products Panel and the Product Code for the device is DZE.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514. Voluntary standards with which the Quantum Versatility Dental Implant System complies include American Society for

Testing and Materials (ASTM) designation F-136 (Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications) and ANSI/AAMI/ISO 11137 (Sterilization of Health Care Products - Radiation Sterilization).

PACKAGING/LABELING/PRODUCT INFORMATION

Advertising material to be used for promotion of the Quantum Versatility Dental Implant System will be consistent with the indications for use and other material shown herein.

Quantum dental implants are packaged in a radiation sterilizable package consisting of an outer tamper evident container (e.g., a printed cardstock sleeve enclosing a vacuum formed tray with a heat sealed Tyvek lid) and an inner plastic bag. Sterilization is accomplished by means of Co^{60} gamma irradiation. Sterilization will be validated by the bioburden method, using ANSI/AAMI/ISO 11137 (Sterilization of Health Care Products - Radiation Sterilization). Abutments and instruments will be packaged either sterile in a system similar to the implant packaging or non-sterile in plastic bags.

INTENDED USE

The Quantum Versatility Dental Implant System is intended for implantation into a partially or fully edentulous mandible or maxilla for the support of single or multiple-tooth prostheses including fixed or removable complete dentures.

DEVICE DESCRIPTION

Design Characteristics

The Quantum Versatility Dental Implant System is composed of both threaded (screw-type) and grooved (fin-type) tapered implants and a solid conical abutment that attaches to the implant with a modified Morse taper connection. This submission covers the grooved (fin-type) implant with a machined, passivated (acid etched) surface, the grooved implant with a resorbable blast media treated (RBM) or medical grade aluminum oxide blasted surface, the grooved implant with a titanium plasma spray (TPS) coated surface, the grooved implant with a plasma-sprayed hydroxyapatite (HA) coated surface and threaded (screw-type) implants with aluminum oxide blasted, RBM treated, TPS coated or HA coated surfaces.

The implant is available in diameters from 3.5 mm to 5.0 mm and in lengths from 8 mm to 20 mm. The system includes surgical instruments such as drills, surgical analog trials and inserters.

Material Composition

Implants and abutments for the Quantum Versatility Dental Implant System are made from titanium-aluminum-vanadium alloy that meets ASTM designation F-136 (Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications). Quantum implants are available with a machined surface, with a machined and passivated (acid etched) surface, with a resorbable blast media (RBM) treated surface, with a surface that is blasted with medical grade aluminum oxide, coated with plasma-sprayed titanium (TPS) or coated with a 50 μm thick layer of plasma-sprayed hydroxyapatite (HA) to facilitate attachment of bone. The use of titanium and titanium alloy, either machined, acid etched, with blasted surfaces or with HA coatings, is widespread in commercially distributed, permanently implanted medical devices and the materials are widely considered to be biocompatible. Titanium is often used as a negative control in biocompatibility testing.

EQUIVALENCE TO MARKETED PRODUCT

Quantum BioEngineering, Ltd. submits the following information to demonstrate that the Quantum Versatility Dental Implant System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices: the Bicon Dental Implant (K853788, K875243, K875242), the Steri-Oss Replace HA-Coated Implant (K962845), BioHorizons Dental Implants (K964330, K972313, K960026), Simpler Threaded Implants (K974401, K974402, K974856, K974857) and Brånemark Fixture (K820013, K841551, K925764, K925765, K934825).

Intended Uses

The indications for use for the Quantum Versatility Dental Implant System and the predicate devices are substantially the same. All are intended for implantation into a partially or fully edentulous mandible or maxilla for the support of single or multiple-tooth prostheses including fixed or removable complete dentures.

Design and Materials

The design and functional characteristics of the Quantum Versatility Dental Implant System and the Bicon Dental Implant are similar in their use of a tapered, grooved design. The grooves are intended to provide macroretention in bone and to increase the surface area for bone attachment relative to a smooth design. The threads of the threaded Quantum Versatility Dental Implant, the BioHorizons Dental Implant and the Steri-Oss Replace HA-Coated Implant serve a similar function, and those implants also have a tapered design. The Bicon Dental Implant shares with the Quantum Versatility Dental Implant System the method of attaching the abutment to the implant using a modified Morse taper. The Quantum implant shares the use of Ti-6Al-4V with all the predicate devices except the Steri-Oss and Brånemark implants, as well as with numerous other marketed implants. It shares the use of an HA coating with the Bicon Dental Implant, the

Steri-Oss Replace HA-Coated Implant, the BioHorizons implant and numerous other marketed implants.

Engineering Evaluation

A design comparison among the Quantum Versatility Implant, Bicon Dental Implant and BioHorizons Dental Implant has been made by an independent academic institution. It was concluded that the Quantum, Bicon and BioHorizons implants are approximately equivalent. It was noted that the Quantum implant has greater resistance to deformation than the Bicon and BioHorizons implants and has a greater section modulus. In short, the Quantum implant is more robust than the predicate devices and is less subject to deformation that could damage the HA coating.

Hydroxyapatite Coating Characteristics

The Quantum Versatility Dental Implant System HA coating has crystallinity, purity and mechanical properties at least as high as those of the coatings on currently marketed devices and at least as high as the suggestions of the FDA Guidance Document.[1]

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[1] *Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants*. Division of General and Restorative Devices, November 11, 1992.

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE

The Quantum Versatility Dental Implant System is substantially equivalent to the Bicon Dental Implant, the Steri-Oss Replace HA-Coated Implant, BioHorizons Dental Implants, the Simpler Implant and the Brånemark Fixture in the following respects:

	Subject Device	Predicate Devices				
	Quantum Versatility Dental Implant System	Bicon Dental Implant (K853788, K875243, K875242)	Steri-Oss Replace HA-Coated Implant (K962845)	BioHorizons Dental Implants (K964330, K972313, K960026)	Simpler Threaded Implant (K974401, K974402, K974856, K974857)	Brånemark Fixture (K820013, K841551, K925764, K925765, K934825)
INTENDED USE						
Implantation into a partially or fully edentulous mandible or maxilla for the support of single or multiple-tooth prostheses including fixed or removable complete dentures.	YES	YES	YES	YES	YES	YES
DESIGN						
Body shape	tapered	tapered	tapered	tapered	tapered	straight
Mechanical retention features	grooves or threads	grooves	threads	threads	threads	threads
Cross-section of thread or groove	modified square	modified square	buttress	square	square	V-thread
Single-stage or two-stage design	either	either	two-stage	two-stage	either	two-stage
Method of abutment attachment to implant	taper joint or screw	taper joint	screw	screw	taper joint	screw
Available diameters, mm	3.5 to 5.0	3.5 to 5.0	4.3 to 6.0	3.5 to 5.0	3.25 to 4.0	3.75 to 5.5
Available lengths, mm	8 to 20	8 to 14	10 to 16	9 to 13	8 to 15	7 to 20
Solid abutment for cemented restorations	YES	YES	YES	YES	YES	YES

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE (continued)

	Subject Device	Predicate Devices				
	Quantum Versatility Dental Implant System	Bicon Dental Implant (K853788, K875243, K875242)	Steri-Oss Replace HA-Coated Implant (K962845)	BioHorizons Dental Implants (K964330, K972313, K960026)	Simpler Threaded Implant (K974401, K974402, K974856, K974857)	Brånemark Fixture (K820013, K841551, K925764, K925765, K934825)
MATERIALS						
Implant body and abutment	Ti-6Al-4V	Ti-6Al-4V	CP Ti (abutments, Ti alloy)	Ti-6Al-4V	Ti-6Al-4V	CP Ti
Coatings and surface treatments available	TPS, HA, RBM, Grit Blasted, Uncoated (passivated)	TPS, HA, Uncoated	HA	TPS, HA, RBM	Grit Blasted	Uncoated

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2001

Mr. Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, California 92130

Re: K002241
Trade Name: Quantum Versatility Dental Implant System
Regulatory Class: III
Product Code: DZE
Dated: July 20, 2000
Received: July 24, 2000

Dear Mr. Larson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002241

Device Name: Quantum™ Versatility Dental Implant System

Indications for Use:

Intended for implantation into a partially or fully edentulous mandible or maxilla for the support of single or multiple-tooth prostheses including fixed or removable complete dentures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number 002241